IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Maino et al.

Serial No.

08/803,702

Filed:

February 21, 1997

For:

METHOD FOR DETECTING T CELL RESPONSE

TO SPECIFIC ANTIGENS IN WHOLE BLOOD

Group Art Unit

1642

Examiner

Phillip Gambel, Ph.D.

Hon. Assistant Commissioner for Patents

BOX DAC

Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicant hereby makes the

following documents of record in the above identified application:

U.S. Patents

5,407,805

Seon

04/1995

5,093,234

Schwartz

03/1992

Foreign Patent Documents

^{*}Applicants reserve the right to challenge the status of any of the cited documents as prior art.

Publications

Becton Dickinson Immunocytometry Systems, "Detection of Intracellular Cytokines in Activated Lymphocytes," <u>Application Note 1</u>, 1-12 (1997).

Brett, S.J. et al., "Limiting Dilution Analysis of the Human T Cell Response to Mycobacterial Antigens from BCG Vaccinated Individuals and Leprosy Patients," Clin. Exp. Immunol., 68:510-520 (1987).

Bucy, R.P. et al., "Heterogeneity of Single Cell Cytokine Gene Expression in Clonal T Cell Populations," J. Exp. Med., 180:1251-1262 (1994).

Clouse, K.A. et al., "Enumeration of Viral Antigen-Reactive Helper T Lymphocytes in Human Peripheral Blood by Limiting Dilution for Analysis of Viral Antigen-Reactive T-Cell Pools in Virus-Seropositive and Virus-Seronegative Individuals,"

J. Clin. Microbiol., 27(10):2316-2323 (1989).

Davis, M.M. et al., "Ligand Recognition by αβ T Cell Receptors," <u>Annu. Rev. Immunol.</u>, 16:523-544 (1998).

Del Prete, G.F. et al., "Purified Protein Derivative of *Mycobacterium tuberculosis* and Excretory-Secretory Antigen(s) of *Toxocara canis* Expand In Vitro Human T Cells with Stable and Opposite (Type 1 T Helper or Type 2 T Helper) Profile of Cytokine Production," J. Clin. Invest., 88:346-350 (1991).

Dobrescu, D. et al., "Enhanced HIV-1 Replication in V β 12 T Cells Due to Human Cytomegalovirus in Monocytes: Evidence for a Putative Herpesvirus Superantigen," Cell, 82:753-763 (1995).

Doherty, P.C., "Cell Mediated Immunity in Virus Infections," <u>Scand. J. Immunol.</u>, 46:528-540 (1997).

ElGhazali, G.E.B. et al., "Number of Interleukin-4- and Interferon-γ-secreting Human T Cells Reactive with Tetanus Toxoid and the Mycobacterial Antigen PPD or Phytohemagglutinin: Distinct Response Profiles Depending on the Type of Antigen Used for Activation," <u>Eur. J. Immunol.</u>, 23:2740-2745 (1993).

Germain, R.N., "The Biochemistry and Cell Biology of Antigen Processing and Presentation," <u>Annu. Rev. Immunol.</u>, 11:403-450 (1993).

Jung, T. et al., "Detection of Intracellular Cytokines by Flow Cytometry," J. Immun. Methods, 159:197-207 (1993).

Kabelitz, D. et al., "Activation-Induced Cell Death (apoptosis) of Mature Peripheral T Lymphocytes," <u>Immunol Today</u>, 14:338-339 (1993).

Komanduri, K.V. et al., "Restoration of Cytomegalovirus-specific CD4⁺ T-lymphocyte Responses After Ganciclovir and Highly Active Antiretroviral Therapy in Individuals Infected with HIV-1," Nature Medicine, 4(8):953-956 (1998).

Lanzavecchia, A. et al., "From TCR Engagement to T Cell Activation: A Kinetic View of T Cell Behavior," Cell, 96:1-4 (1999).

Lolli, F. et al., "HIV Antigen-Reactive T Cells Detected by Antigen-Induced Interferon γ Secretion," <u>AIDS Res. and Human Retroviruses</u>, 10(2):115-120 (1994).

Lolli, F. et al., "T and B Cell Responses to Cytomegalovirus Antigens in Healthy Blood Donors and Bone Marrow Transplant Recipients," <u>FEMS Immun. and Med. Microbiol.</u>, 7:55-62 (1993).

Maino, V.C. et al., <u>Fast Immune Assay System</u>, Becton Dickinson Immunocytometry Systems.

Mellman, I. et al., "Lonely MHC Molecules Seeking Immunogenic Peptides for Meaningful Relationships," <u>Current Opinion in Cell Biology</u>, 7(4):564-572 (1995).

Meyaard, L. et al., "Single-Cell Analysis of Il-4 and IFN-γ Production by T Cells from HIV-Infected Individuals," J. of Immun., 157:2712-2718 (1996).

Openshaw, P. et al., "Heterogeneity of Intracellular Cytokine Synthesis at the Single-Cell Level in Polarized T Helper 1 and T Helper 2 Populations," <u>J. Exp. Med.</u>, 182:1357-1367 (1995).

Picker, L.J. et al., "Direct Demonstration of Cytokine Synthesis Heterogeneity Among Human Memory/Effector T Cells by Flow Cytometry," <u>Blood</u>, 86(4):1408-1419 (1995).

Prussin, C. et al., "Detection of Intracytoplasmic Cytokine Using Flow Cytometry and Directly Conjugated Anti-cytokine Antibodies," J. Immun. Methods, 188:117-128 (1995).

Russell, J.H., "Activation-induced Death of Mature T Cells in the Regulation of Immune Responses," <u>Current Opinion in Immunology</u>, 7:382-388 (1995).

Salmon, M. et al., "Production of Lymphokine mRNA by CD45R⁺ and CD45R⁻ Helper T Cells from Human Peripheral Blood and by Human CD4⁺ T Cell Clones," <u>J. Immunol.</u>, 143(3):907-912 (1989).

Sornasse, T. et al., "Differentiation and Stability of T Helper 1 and 2 Cells Derived from Naive Human Neonatal CD4⁺ T Cells, Analyzed at the Single-cell Level," <u>J. Exp. Med.</u>, 184:473-483 (1996).

Suni, M.A. et al., "Detection of Antigen-Specific T Cell Cytokine Expression in Whole Blood by Flow Cytometry," J. Immunol. Meth., 212:89-98 (1998).

Surcel, H.-M. et al., "Th1/Th2 Profiles in Tuberculosis, Based on the Proliferation and Cytokine Response of Blood Lymphocytes to Mycobacterial Antigens," <u>Immunology</u>, 81:171-176 (1994).

Waldrop, S.L. et al., "Determination of Antigen-specific Memory/Effector CD4⁺ T Cell Frequencies by Flow Cytometry," <u>J. Clin. Invest.</u>, 99(7):1739-1750 (1997).

Waldrop, S.L. et al., "Normal Human CD4" Memory T Cells Display Broad Heterogeneity in Their Activation Threshold for Cytokine Synthesis," J. Immun., 161:5284-5295 (1998).

Weaver, D. J. Jr. et al., "Macrophage Mediated Processing of an Exogenous Antigenic Fluorescent Probe: Time-dependent Elucidation of the Processing Pathway," <u>Cell</u>, 87:95-104 (1996).

Zunino, S.J. et al., "Immunodetection of Histone Epitopes Correlates with Early Stages of Apoptosis in Activated Human Peripheral T Lymphocytes," <u>Amer. J. Path.</u>, 149(2):653-663 (1996).

Copies of the aforementioned documents, which are listed on the accompanying Form PTO-1449 (submitted in duplicate), are enclosed herewith.

It is respectfully requested that these documents be (1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) printed on any patent that may issue on this application. Applicants request that a copy of Form PTO-1449 (submitted in duplicate herewith), as considered and initialed by the Examiner, be returned with the next communication.

A check in the amount required under 37. C.F.R.§ 1.97(c) is enclosed

herewith.

An early and favorable action is respectfully requested.

Respectfully submitted,

MARCH 5 1999

Daniel M. Becker Reg. No. 38,376

Attorney for Applicants

I hereby Certify that this Correspondence is being Deposited with the U.S. Postal Service as First Class Mail in an Envelope Addressed to: ASSISTANT COMMISSIONER FOR PATENTS WASHINGTON, D.C. 20231, ON

Signature of Person Signing

c/o FISH & NEAVE

1251 Avenue of the Americas New York, N. Y. 10020

(650) 617-4000